

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effect of preconception counseling on health promoting behaviors of reproductive age women

Protocol summary

Summary

This study aimed to investigate the effect of educational intervention on promoting healthy behaviors of reproductive age women in Sari city. Methods: This study is a randomized controlled trial, that 104 women in childbearing age that randomly selected in SARI city and assigned to intervention and control groups (n=52). Inclusion criteria was women who willing childbearing at age 18-40, physical and mental wellness, lack of the history of mental illness, lack of addiction, residence in the city of Sari and exclusion criteria was not wanting to continue participation in the study and relocation and migration from Sari city. The data collection tool was social demographic questionnaire (has 15 questions: demographic data and history of pregnancy) and health promoting life style (HPLP-II) questionnaire, Including 6 dimension: health responsibility, physical activity, nutritional status, spiritual growth, stress management and interpersonal relationship. According to information obtained from the pre-test stage, educational intervention about the dimension of health promoting behaviors were conducted for intervention group. To intervention group, was used of pamphlets and training package prepared by the researcher. Intervention program was including educational sessions and once a week. A month after the intervention, data (Scores of dimension of health promoting behaviors) collected using the same basic questionnaire in two groups, and were analyzed with parametric and non parametric tests. Keywords: Preconception counseling, health promotion, reproductive age, health promoting behaviors

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016030226879N1**

Registration date: **2016-04-04, 1395/01/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-04, 1395/01/16

Registrant information

Name

marzieh shabani chepi

Name of organization / entity

health school of guilan university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 11 4203 8293

Email address

mshabani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preconception counseling on health promoting behaviors of reproductive age women

Public title

Effect of Preconception Counseling on Health Promoting

Behaviors

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18 and 40 years; being physically and mentally healthy; lack of addiction; have at least read and write; fill informed consent to participate in the study; residence in the city of Sari.

Exclusion criteria: Not wanting to continue participation in the study; relocation and migration from the city of Sari.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

School of Health, Guilan University of Medical Sciences, Resalat street, Rasht, Iran.

City

Rasht

Postal code

-

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

1930596722

Health conditions studied

1

Description of health condition studied

Relationship of preconception counseling on health promoting behaviors of reproductive age women

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Health responsibility

Timepoint

Before and one month after the intervention

Method of measurement

Health-promoting lifestyle questionnaire score

2

Description

physical activity

Timepoint

Before and one month after the intervention

Method of measurement

Health-promoting lifestyle questionnaire score

3

Description

nutrition status

Timepoint

Before and one month after the intervention

Method of measurement

Health-promoting lifestyle questionnaire score

4

Description

spiritual growth

Timepoint

Before and one month after the intervention

Method of measurement

Health-promoting lifestyle questionnaire score

5

Description

interpersonal relationships

Timepoint

Before and one month after the intervention

Method of measurement

Health-promoting lifestyle questionnaire score

6

Description

stress management

Timepoint

Before and one month after the intervention

Method of measurement

Health-promoting lifestyle questionnaire score

7

Description

total score of health promoting behaviors

Timepoint

Before and one month after the intervention

Method of measurement

Health-promoting lifestyle questionnaire score

Secondary outcomes

empty

Intervention groups

1

Description

interventional group: after selecting the desired samples according to the criteria, questionnaires will be distributed and completed. According to information obtained from the pre-test stage, educational needs of research units determined and educational intervention conducted for intervention group. For test groups used the training package prepared by the researcher. Intervention program including educational sessions and once a week. A month after the intervention, data collected using the same basic questionnaire in two groups.

Category

Lifestyle

2

Description

Control group: for control group, like the clients of other health centers is used of booklet,s Safe Motherhood national program: integrated maternal health care the Ministry of Health". Preconception counseling be done in 1-2 sessions Individually.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 8 and 5 Sari

Full name of responsible person

Marzieh Shabani Chepi, master of health education

Street address

Health Center No. 8 and 5, Sari, Mazandaran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Azari, Research Assistant

Street address

School of Health, Guilan University of Medical Sciences, Resalat street, Rasht, Iran.

City

Rasht

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Health, Guilan University of Medical Sciences

Full name of responsible person

Marzieh Shabani Chepi

Position

Student - MA

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty